STATUS OF THE CLAIMS

The status of the claims after this amendment is as follows:

Claims 1-5 are canceled;

Claims 6-16 are pending and amended as indicated;

Claims 17-20 are canceled;

Claims 21-30 are new.

RESTRICTION/ELECTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 are drawn to a mucoadhesive composition comprising: either an anti-migraine drug or an anti-nausea drug; either a lipophilic carrier or a hydrophilic carrier; a mucoadhesive agent; and a sorption promoter, as classified in class 514, subclass 967.

II. Claims 6-11 are drawn to a method for treating either migraine and headache, or nausea and vomiting, comprising intravaginally administering a formulation of said mucoadhesive composition, as classified in class 424, subclass 430.

III. Claims 6-20 are drawn to an intravaginal device and a method for treating either migraine and headache, or nausea and vomiting, comprising intravaginally administering said intravaginal device, which has a formulation of said mucoadhesive composition incorporated therein or coated thereon, as classified in class 604, subclass 279.

1. Inventions I and II are related as a product and a method of using said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the

product as claimed can be used by another method that is materially different from the instantly claimed method of using said product See MPEP § 806.05(h). In the instant case, a product as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention II. For example, as opposed to administering said mucoadhesive composition intravaginally as claimed in Invention II, a formulation of said mucoadhesive composition may alternatively be administered sublingually as opposed to intra vaginally, wherein said mucoadhesive composition may further comprise a diuretic to offset water retention (i.e., "bloating"), which is often associated with menstruation.

Inventions I and III are related as a product and a method of using said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a product as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention III. For example, as opposed to intravaginally administering said mucoadhesive composition, which has been incorporated on or within an intravaginal device as claimed in Invention III, a formulation of said mucoadhesive composition may alternatively be directly administered sublingually without the aid of a delivery device.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as

capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Inventions II has a materially different mode of operation with respect to the method claimed in Invention III. More specifically, the method claimed in Invention II has a mode of operation of intravaginally administering a formulation of said mucoadhesive composition directly into the vagina without the aid of a delivery device, whereas the method claimed in Invention III has a mode of operation that requires an intravaginal delivery device for intravaginally administering a formulation of said mucoadhesive composition into the vagina. As a result, the method claimed in Invention II has a materially different mode of operation from the method claimed in Invention III, and are therefore unrelated. Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden. As a result, restriction for examination purposes as indicated is proper. Applicants are therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

Applicants elect, with traverse, to prosecute Group II, directed to claims 6-11.

2. Claims 1, 3-6, 9-13 and 15-17 are generic to a plurality of disclosed patentably distinct species of drug, namely anti-migraine drugs and anti-nausea drugs, and subspecies thereof, such as ergotamine and metoclopramide, respectively. The disclosed species and subspecies are patentably distinct, each from the other, because they possess different molecular

structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect not only a single disclosed patentably distinct species of drug (i.e., an anti-migraine drug), but also a single disclosed patentably distinct subspecies thereof (i.e., ergotamine), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 3-6, 9-13 and 15-17 are generic. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification.

Applicants elect, with traverse, to prosecute species directed to the anti-migraine drug, with subspecies directed to the drug almotriptane.

Applicants traverse Examiner's requirement on the basis that different chemical structures and different chemical and physical properties of these compounds play no role in the invention, as long as they can be successfully formulated according to the invention. The only difference that matters is their hydro or lipophilicity that affect the selection of either hydrophilic carrier (if the drug is lipophilic) or lipophilic carrier (if the drug is hydrophilic). Moreover, the majority of the claimed anti-migraine drugs are triptans, chemically defined indole derivatives, similar in the chemical structure and function.

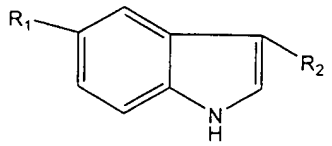
The triptans, which are chemically defined indole derivatives of chemical formulae as shown in Table 1. The mechanisms of action of all triptans are similar and depend on

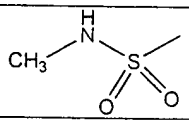
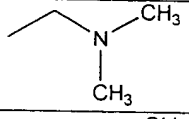
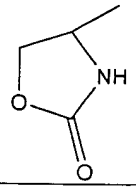
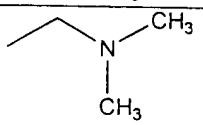
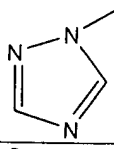
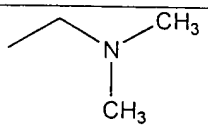
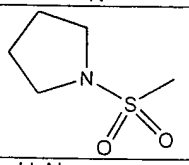
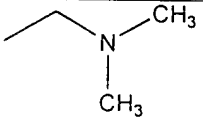
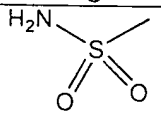
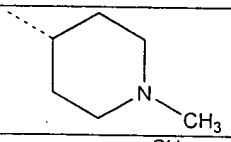
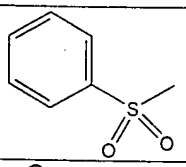
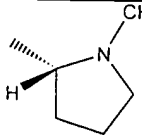
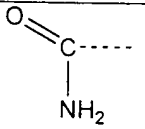
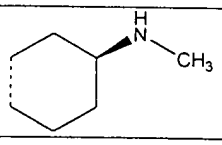
stimulation of specific serotonin or 5-hydroxytryptamine (5-HT) receptors, including peripheral 1B and central and peripheral 1D receptor subtypes. Different pharmacokinetic properties among the various triptans reflecting the chemical diversity within this drug class have translated clinically into a therapeutic strength as the physician can optimize migraine symptom management by selecting the most advantageous triptan according to individual patient needs. To comply with 35 U.S.C § 121, the applicant elects almotriptan ($C_{17}H_{25}N_3O_2S$, MW = 335, see Table 1), which has the efficacy of sumatriptan with a more favorable adverse event profile, as a single disclosed patentably distinct subspecies of the triptans for prosecution.

Nevertheless, as the method claimed in this invention overcomes the major limitations common to all triptans used with conventional oral migraine therapy, it is submitted that the merits of the claims restricted to almotriptan will apply to other members of the triptan family as well as other anti-migraine drugs claimed herein because the method of treatment of the migraine or nausea depends on the formulation of the drug in the unique formulation permitting the mucoadhesion of the composition to the vaginal wall, release of the drug from the composition and penetration of the drug through the vaginal wall.

Examiner is respectfully requested to examine all at least the triptan compounds of which structure are shown in Table 1.

Table 1: Chemical structures of triptan antimigraine drugs



R_1 =	R_2 =	Empirical Formula	Molecular Weight	INN [a]
		$C_{14}H_{21}N_3O_2S$	295	sumatriptan
		$C_{16}H_{21}N_3O_2$	287	zolmitriptan
		$C_{15}H_{19}N_5$	269	rizatriptan
		$C_{17}H_{25}N_3O_2S$	335	almotriptan
		$C_{17}H_{25}N_3O_2S$	335	naratriptan
		$C_{22}H_{26}N_2O_2S$	382	eletriptan
		$C_{14}H_{17}N_3O$	243	frovatriptan

[a] International nonproprietary name as defined by the World Health Organization

Species Election Requirement (Sections 3-5)

With regard to sections 3-5, Applicants respectfully submit that a modified variation of the current composition has been examined in six issued U. S. patents and numerous other pending applications and the restriction requirement with respect to the individual components of the composition was never required.

Applicants respectfully request Examiner to reconsider and withdraw his species election listed in the sections 3-5.

3. Claims 1-3, 6 and 17 are generic to a plurality of disclosed patentably distinct species of carrier, namely lipophilic carriers and hydrophilic carriers, and subspecies thereof, such as a mono glyceride fatty acid having a C_8 to C_{18} chain, or a polyethylene glycol having a molecular weight between about 200 and 8000, respectively. The disclosed species and subspecies are patentably distinct, each from the other, because they possess different molecular structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect not only a single disclosed patentably distinct species of carrier (i.e., a lipophilic carrier), but also a single disclosed patentably distinct subspecies thereof (i.e., a monoglyceride fatty acid having a C_8 to C_{18} chain), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1-3, 6 and 17 are generic. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification.

However, to be responsive, Applicants elect, with traverse,

to prosecute species directed to a hydrophilic carrier, with subspecies directed to polyethylene oxide, having a chemical formula $H(OCH_2CH_2)_nOH$.

Although the election of species was made in order to be responsive, Applicants submits that the general comments vis-a-vis sections 3-5 apply here.

4. Claims 1, 2, 6 and 17 are generic to a plurality of disclosed patentably distinct species of mucoadhesive agent (i.e., hydroxypropyl methylcellulose). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of mucoadhesive agent (i.e., hydroxypropyl methylcellulose) for prosecution on the merits to which the claims shall be restricted if no generic claim is fillally held allowable. Currently, claims 1, 2, 6 and 17 are generic. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification.

Applicants elect, with traverse, to prosecute species directed to mucoadhesive agent with subspecies directed to hydroxypropyl methylcellulose having a general chemical formula $C_6H_7O_2(OH)z(OCH3)x$.

Although the election of species was made in order to be responsive, Applicants submits that the general comments vis-a-vis sections 3-5 apply here.

5. Claims 1, 2, 6 and 17 are generic to a plurality of

disclosed patentably distinct species of sorption promoters (i.e., ethoxydiglycol). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of sorption promoter (i.e., ethoxydiglycol) for prosecution on the merits to which, the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 2, 6 and 17 are generic. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification.

Applicants elect, with traverse, to prosecute species directed to sorption promoters, with subspecies directed to ethoxydiglycol, also known as diethylene glycol having a chemical formula $HOCH_2CH_2OCH_2CH_2OH$.

Although the election of species was made in order to be responsive, Applicants submits that the general comments vis-a-vis sections 3-5 apply here.

6. Claims 7, 8 and 20 are generic to a plurality of disclosed patentably distinct species of formulation (i.e., cream). The disclosed species are patentably distinct, each from the other, because they possess different physical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed

patentably distinct species of formulation (i.e., cream) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 7, 8 and 20 are generic.

Applicants elect, with traverse, to prosecute species directed to a film formulation.

7. Claims 8, 12-14 and 17-20 are generic to a plurality of disclosed patentably distinct species of intravaginal device (i.e., tampon). The disclosed species are patentably distinct, each from the other, because they possess different physical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of intravaginal device (i.e., tampon) for prosecution on the merits to which the claims shall he restricted if no generic claim is finally held allowable. Currently, claims 8, 12-14 and 17-20 are generic.

Applicants elect, with traverse, to prosecute species directed to intravaginal device directed to a tampon and tampon-like device.

Conclusion to Restriction Requirement

Applicants have responded to the Examiner's requirement regarding the restriction between product and methods of use claims.

Applicants expect Examiner to act on his statements that where Applicant elects claims directed to a product or a method, and the product or the method claim is subsequently found allowable, withdrawn product or method claims that depend from or otherwise include all the limitations of the allowable product

claim will be rejoined in accordance with the provisions of MPEP § 821.04 and that in the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of using claims will be withdrawn.

Applicants are following up on Examiner's statement that, additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants should amend methods of using claims either to maintain dependency on the product claims or to otherwise include the limitations of the product claims in order to prevent a loss of the right to rejoinder.

Applicants are advised by the Examiner that a fully responsive reply to this requirement must include an explicit identification of a single disclosed patentably distinct species of: drug (i.e., an anti-migraine drug) and subspecies thereof (i.e., ergotamine); carrier (i.e., a lipophilic carrier) and subspecies thereof (i.e., a monoglyceride fatty acid having a C_8 to C_{18} chain); mucoadhesive agent (i.e., hydroxypropyl methylcellulose); sorption promoter (i.e., ethoxydiglycol); formulation (i.e., cream); and intravaginal device (i.e., tampon), that is elected consonant with this requirement.

Applicants made all required election with traverse.

Examiner also remind Applicants that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i). Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP §

812.01.

Inventorship of all claims remains the same.

SUMMARY

In summary, Applicants made election of groups, species and subspecies as requested, with traverse, and submit herein arguments in support of their traverse.

Examination of all pending, amended and added claims is respectfully requested.

Dated: August 29, 2006

Respectfully Submitted,

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